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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,775	09/15/2003	Andrea Marinello	930071-2001	2185

20999 7590 12/26/2006  
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EXAMINER

GHALI, ISIS A D

ART UNIT	PAPER NUMBER
	1615

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/26/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/662,775	MARINELLO ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Isis A. Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 06 October 2006.

2a) This action is FINAL.                  2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-33 is/are pending in the application.

4a) Of the above claim(s) 1-12 and 31-33 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 13-30 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>3/15/2004</u> .	5) <input type="checkbox"/> Notice of Informal Patent Application
	6) <input type="checkbox"/> Other: _____ .

## DETAILED ACTION

The receipt is acknowledged of IDS filed 03/15/2004; and applicants' election filed 10/06/2006.

### ***Response to Election/Restrictions***

1. Applicant's election of Group II, claims 13-30 in the reply filed on 10/06/2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Claims 1-12 and 31-33 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/06/2006.

Claims 13-30 are included in the prosecution.

### ***Priority***

3. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Italy on September 25, 2002. It is noted, however, that applicant has

not filed a certified copy of the VR 2002A000094 application as required by 35 U.S.C. 119(b).

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 13-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection. Claims 13 and 25 do not describe where the compress is located in the device in relation to the mask and the inflatable pad. No correlation between the position of the mask and the inflatable pad to the compress. Claim 30 is drawn to "method for treating sinusitis comprising the steps of squeezing the compress to force out the active ingredient; opening skin pores to which pressure is applied; and forcing the active ingredient through the opened skin pores of a person in the direction of an inflammation". The specification does not describe how active ingredients will be directed in direction of an inflammation. The expression "in the direction of an inflammation" does not convey to one of ordinary skill in the art that applicants were in possession of the claimed subject matter. The claim language recited without any correlation between applying the device

and direction of the active ingredients to the inflammation, and does not meet the written description requirement for delivering active ingredients in the direction of inflammation.

Claims employing language at the point of novelty, such as applicants', neither provide those elements required to practice the inventions, nor "inform the public" during the life of the patent of the limits of the monopoly asserted. This expression represents only an invitation to experiment regarding possible means.

To satisfy the Written description requirement, applicant must convey with reasonable clarity to one skilled in the art, as of the filing date that applicant were in possession of the claimed invention.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 13-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 13-30 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: relation of the compress with the inflatable pad or the facial mask.

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Regarding claim 19, the term “pump” does not set forth the metes and bounds of the claim. Recourse to the specification does not define the term. Is it electric pump, or manual pump?

Claim 24 recites the mask comprises plastic, while at page 6, lines 26-27, applicants disclosed that “the mask is made of plastic”, and not only comprises plastic.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 13, 15-25, 27-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2,262,711 ('711) in view of US 4,93,401 ('401).

US '711 teaches medical nebulizer used for treating sinusitis (col.1, lines 1-5). The nebulizer comprises mask, medicament in a chamber, and pressure provided by motor to vaporize the medicine to small pores of the sinus tract (col.1, lines 13-39). The medicaments are contained in a sponge member (col.3, lines 21-23).

Although US '711 suggests pressure to deliver of the medication, however, it does not teach the inflatable pad as required by claims 13 and 25, or means to secure the mask to the person's head as claimed in claims 20 and 29.

US '401 teaches mask to deliver medicament to the underlying tissues, the mask comprises medicament impregnated in a pad and delivered by force of inflatable elastic pump in order to concentrate the medicaments and inject them as near as possible to the injured or inflamed part (abstract; col.2, lines 55-61, col.3, lines 24-28, 39-40; figure 1). Figure 3 shows the mask is supplied by strips to affix the mask to the patient's head.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide device comprising mask, medicament contained in a sponge member, and pressure to deliver the medicine to the sinuses as disclosed by US '711, and use the inflatable elastic pump to deliver the medicaments from the sponge member as disclosed by US '401, motivated by the of US '401 that such a pressure elastic pump concentrates the medicaments and injects them as near as possible to the injured or inflamed part, with reasonable expectation of having device comprising mask, medicament contained in a sponge member, and elastic pump to

deliver the medicine as near as possible to the injured or inflamed part including sinuses with great success. Additionally, one having ordinary skill in the art would have added the strips used to affix the mask disclosed by US '401 to the mask of US '711 motivated by the teaching of US '401 that such strips secure the device to the head of user, with reasonable expectation of having device comprising mask that has strips to secure the mask to the face of the user.

11. Claims 14 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '711 in view of US '401, and further in view of US 5,248,504 ('504).

The combined teachings of US '711 and US '401 are discussed above. However, the combined teachings of the references do not teach allyl isothiocyanate as an active ingredient to be delivered to the sinuses as claimed by claims 14 and 26.

US '504 teaches method for treating nasal sinuses dysfunction comprising applying allyl isothiocyanate to the affected mucosa by spraying (abstract; col.2, lines 20-22, 35-39, 50-52).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide device comprising mask, medicament contained in a sponge member, and elastic pump to deliver the medicine as near as possible to the injured or inflamed sinuses as disclosed by the combined teachings of US '711 and US '401, and replace the medicament by allyl isothiocyanate disclosed by US '504, motivated by the teaching of US '504 that allyl isothiocyanate treats nasal sinuses dysfunction when applied to the affected mucosa, with reasonable expectation of having

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device comprising mask, allyl isothiocyanate contained in a sponge member, and elastic pump that treats nasal sinuses dysfunction with great success.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Isis A Ghali  
Primary Examiner  
Art Unit 1615

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